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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/721,183	11/22/2000	Susana Salceda	DEX-0117	1493

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EXAMINER	
CANELLA, KAREN A	
ART UNIT	**PAPER NUMBER**
1643	

DATE MAILED: 06/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/721,183	SALCEDA ET AL	
	Examiner	Art Unit	
	Karen A. Canella	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *7,18-20,22-24,26-28,30-32,34-36 and 38-82* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *7,18-20,22-24,26-28,30-32,34-36 and 38-82* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/11/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 21, 25, 29, 33 and 37 have been canceled. Claims 3-7, 18, 22, 26, 30 and 34 have been amended. Claims 38-82 have been added. Claims 37, 18-20, 22-24, 26-28, 30-32, 34-36 and 38-82 are pending and under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 37, 18-20, 22-24, 26-28, 30-32, 34-36 and 38-46, 49, 50, 53, 54, 57, 58, , 61, 62, 65, 66, 69, 70, 73, 74, , 77, 78, 81 and 82 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for method of determining the polynucleotide of SEQ ID NO:1 or 2 in breast tissues or whole blood of patients , does not reasonably provide enablement for a method of determining the polynucleotide of SEQ ID NO1 or 2 in blood derivatives, urine saliva or other bodily secretions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The instant method claims are drawn to encompass the detection of polynucleotides of SEQ ID NO:1 or 2 in the broadly drawn embodiment of "bodily fluids" the specification states that bodily fluids comprise whole blood, plasma, serum, a derivative of blood, urine, saliva or other bodily secretions. It is recognized in the art that breast cancer patients exhibit circulating breast cancer cells in peripheral blood, and that sensitive techniques such as PCR can detect polynucleotides encoding breast cancer specific antigens in such patients, there is no objective evidence in the specification that would give credence to the notion that polynucleotides encoding a breast tumor antigen can be detected in urine, saliva or tears, because breast cancer cells would not be expected to be in such bodily secretions. Plasma and serum represent blood derivatives encompassed by the instant claims which have been depleted of red blood cells and therefore the processes of such depletion would also be expected to deplete circulating breast cancer cells. There is not objective evidence in the specification or any art of record to indicate that plasma or serum from a breast cancer patient would be a source of breast cancer cells or polynucleotides encoding a breast cancer antigen. Further, the term "blood derivative" when given the broadest reasonable interpretation include

such products as hemoglobin, fibrin and blood albumin in addition to serum. As stated above, there is not expectation that said products would contain circulating breast cancer cells or polynucleotides encoding a breast cancer antigen when isolated from a breast cancer patient.

The rejection of claims 3-7 and 18-20, 22-24, 26-28, 30-32, and 34-36 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained for reasons of record Claims 38-82 are also rejected for the same reasons of record.

Claim 3-7 recite the limitation of a polynucleotide which hybridizes under stringent conditions. The recitation of "stringent" conditions does not define the metes and bounds of the physical parameters of the hybridization conditions because "stringent" conditions encompass low, moderate and high stringency. Thus the metes and bounds of the least stringent condition is not defined by the claim and the specification does not provide a definition for stringent hybridization which would set the physical parameters of the hybridization conditions.

Applicant argues that the term "stringent conditions" is well known in the art and is described on pages 21, 22, 27, 32 and 37 of the specification. Upon consultation of the aforesaid pages it was noted that no example of a stringent hybridization condition was given, nor was any limiting definition of stringent hybridization provided. The art recognizes that a stringent hybridization can be of any degree, such as low, medium or high stringency. without any physical parameters to define the stringency, the term "stringent" by itself does not have any limiting function.

The rejection of claims 3-7 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained for reasons of record. Claims 38-82 are also rejected for the same reasons of record. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant method claims are reliant upon the identity of a polynucleotide which hybridizes under undefined conditions to the anti-sense sequence of SEQ ID NO:1. 2 or 18. The specification lacks a definition for "stringent conditions" that would limit the physical parameters of the hybridization, thus the instant claims encompass a genus of polynucleotides which are not limited by sequence similarity to SEQ ID NO:1, 2 or 18. The disclosure of SEQ ID NO:1, 2 and 18 fails to anticipate the claimed genus because the genus tolerates members which differ in structure from SEQ ID NO:1, 2 and 18 and which encode proteins which have a different function from the of the proteins encoded by SEQ ID NO:1, 2 and 18. One of skill in the art would reasonably conclude that applicant was not in possession of the genus of polynucleotides which hybridize to the anti-sense of SEQ ID NO:1, 2 or 18 under any condition of stringency. It logically follows that if applicant was not in possession of the genus of polynucleotides upon which the instant method claims rely, then applicant was not in possession of the instant methods.

Applicant argues that a number of exemplary polynucleotides are described by the specification on pages 27 and 32 which serve to describe the claimed genus of hybridizing polynucleotides. This has been considered but not found persuasive. Only the small probes of SEQ ID NO:9, 10 and 12 and 13 are found on pages 27 and 32. these small probes fail to adequately describe the claimed genus, because the genus encompasses polynucleotides which are variant specie of SEQ ID NO:1, 2 and 18 encompasses an unlimited number of mismatches with the disclosed sequences.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Karen A. Canella, Ph.D.
6/26/2006

KAREN A. CANELLA PH.D
PRIMARY EXAMINER